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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,794	06/08/2001	Suzanne A. W. Fuqua	UTSK:348US/MBW	5270

7590 09/19/2002

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	7

DATE MAILED: 09/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/877,794	Applicant(s) Fuqua et al
	Examiner Ungar	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 8, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-21* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 1-21 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315.We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1 is drawn to a method for detecting tamoxifen-resistant breast cancer cells comprising assaying for any one of seven polypeptides *in vitro*, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 435, subclass 7.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group II. Claims 1 is drawn to a method for detecting tamoxifen-resistant breast cancer cells comprising assaying for any one of seven polypeptides *in vivo*, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The

invention is classified in Class 435, subclass 7.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group III. Claim 2 is drawn to a method for detecting tamoxifen resistant breast cancer cells comprising assaying for two or more of seven polypeptides *in vitro*, each of which is a separate and distinct invention. It is noted that by Factorial Analysis, claim 2 is drawn to 5040 separate and distinct inventions. Applicant is required to elect and specify a single combination of polypeptides to be detected for examination. The invention is classified in Class 435, subclass 7. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group IV. Claim 2 is drawn to a method for detecting tamoxifen resistant breast cancer cells comprising assaying for two or more of seven polypeptides *in vivo*, each of which is a separate and distinct invention. It is noted that by Factorial Analysis, claim 2 is drawn to 5040 separate and distinct inventions. Applicant is required to elect and specify a single combination of polypeptides to be detected for examination. The invention is classified in Class 424, subclass 130.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group V. Claim 3 is drawn to a method of diagnosing tamoxifen-sensitive breast cancer comprising assaying for any one of seven polypeptides *in vitro*, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is

classified in Class 435, subclass 7.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group VI. Claim 3 is drawn to a method of diagnosing tamoxifen-sensitive breast cancer comprising assaying for any one of seven polypeptides *in vivo*, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 424, subclass 130.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group VII. Claim 3 is drawn to a method of diagnosing tamoxifen-resistant breast cancer comprising assaying for any one of seven polypeptides *in vitro*, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 435, subclass 7.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group VIII. Claim 3 is drawn to a method of diagnosing tamoxifen-resistant breast cancer comprising assaying for any one of seven polypeptides *in vivo*, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 424, subclass 130.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group IX. Claim 4 is drawn to a method of predicting tamoxifen resistant breast cancer comprising assaying for any one of seven polypeptides *in vitro*, each of which is a separate and distinct invention. Applicant is required to

elect a single invention for examination. The invention is classified in Class 435, subclass 7.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group X. Claim 4 is drawn to a method of predicting tamoxifen resistant breast cancer comprising assaying for any one of seven polypeptides *in vivo*, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 424, subclass 130.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XI. Claim 5 is drawn to a method of determining survival for an individual with breast cancer in a breast cancer tissue sample from a patient comprising assaying for any one of seven polypeptides, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 435, subclass 7. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XIa. Claim 6 is drawn to a method for detecting tamoxifen-resistant breast cancer cells comprising assaying for any one of seven nucleic acids, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 435, subclass 6. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XII. Claim 7 is drawn to a method for detecting tamoxifen resistant breast cancer cells comprising assaying for two or more of seven polynucleotides, each of which is a separate and distinct invention. It is noted that by Factorial Analysis, claim 7 is drawn to 5040 separate and distinct inventions. Applicant is required to elect and specify a single combination of polynucleotides to be detected for examination. The invention is classified in Class 435, subclass 6. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XIII. Claim 8 is drawn to a method for diagnosing tamoxifen-sensitive breast cancer comprising assaying for any one of seven nucleic acids, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 435, subclass 6. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XIV. Claim 8 is drawn to a method for diagnosing tamoxifen-resistant breast cancer comprising assaying for any one of seven nucleic acids, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 435, subclass 6. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XV. Claim 9 is drawn to a method for predicting likelihood of development of tamoxifen resistant breast cancer comprising assaying for any one of seven nucleic acids, each of which is a separate and distinct invention.

Applicant is required to elect a single invention for examination. The invention is classified in Class 435, subclass 6. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XVI. Claims 9-10 are drawn to a method for predicting/determining patient survival of tamoxifen resistant breast cancer/ comprising assaying for any one of seven nucleic acids, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 435, subclass 6. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XVII. Claim 11 is drawn to a method of altering the phenotype of a breast cancer cell *in vivo* comprising contacting the cell with a gene selected from any one of seven nucleic acids, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 514, subclass 44. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XVIII. Claim 11 is drawn to a method of altering the phenotype of a breast cancer cell *in vitro* comprising contacting the cell with a gene selected from any one of seven nucleic acids, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 536, subclass 23.1. It is noted for

Applicant's convenience that the instant requirement is not an election of species.

Group XIX. Claims 12-13 are drawn to a method of treating breast cancer with an antiangiogenic agent and tamoxifen. The invention is classified in Class 514, subclass 2+.

Group XX. Claim 14 is drawn to a method of treating cancer by providing an antisense construct comprising administering an antisense construct selected from any one of seven nucleic acids, each of which is a separate and distinct invention. Applicant is required to elect a single invention for examination. The invention is classified in Class 514, subclass 44. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XXI. Claim 15 is drawn to a method for treating cancer comprising providing an effective amount of an expression construct containing a gene encoding bFGFR and tamoxifen, classified in Class 514, subclass 44.

Group XXII. Claim 16 is drawn to a kit comprising one or more antibodies that specifically bind to seven different polypeptides. It is noted that by Factorial Analysis, claim 16 is drawn to 5040 separate and distinct inventions. Applicant is required to elect and specify a single combination of antibodies for examination. The invention is classified in Class 530, subclass 387.1 and 389.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XXIII. Claim 17 is drawn to a kit comprising one or more pairs of primers effective to amplify one or more of seven different polynucleotides. It is noted that by Factorial Analysis, claim 16 is drawn to 5040 separate and distinct inventions. Applicant is required to elect and specify a single combination of antibodies for examination. The invention is classified in Class 536, subclass 23.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XXIV. Claim 18 is drawn to a method of detecting markers for tamoxifen resistant breast cancer classified in Class 435, subclass 6.

Group XXV. Claim 19-20 are drawn to a pharmaceutical composition comprising two or more nucleic acids selected from a group of seven nucleic acids. It is noted that by Factorial Analysis, claim 19 is drawn to 5040 separate and distinct inventions. Applicant is required to elect and specify a single combination of nucleic acids for examination. The invention is classified in Class 536, subclass 23.1. It is noted for Applicant's convenience that the instant requirement is not an election of species.

Group XXVI. Claim 21 is drawn to a pharmaceutical composition comprising two or more polypeptides selected from a group of seven polypeptides. It is noted that by Factorial Analysis, claim 21 is drawn to 5040 separate and distinct inventions. Applicant is required to elect and specify a single combination of polypeptides for examination. The invention is classified in Class 530, subclass 300+. It is noted for Applicant's convenience that the instant requirement is not an election of species.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of the Groups of Group XXII/XXIII/XXV/XXVI as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions of the Groups of Group 1- XXI, XXIV-XXIV are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups XXII/XXVI and I-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody products as claimed and the polypeptide products as claimed can be used in materially different processes such as production of anti-idiotypic antibodies and production of antibodies, respectively.

The inventions of Groups XXIII/XXV and XIa-XVIII/XX-XXII/XXIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid products as claimed can be

used in materially different processes such synthesis of the claimed polypeptides and fragments of the claimed polypeptides

The inventions of the Groups of Group XXII/XXIII/XXV/XXVI and XIX are not at all related because the antibody, polypeptides, nucleic acids of the Groups of Group XXII/XXIII/XXV/XXVI are not used in any of the methods of XIX.

The inventions of Groups XXII/XXVI and the methods of the Groups of Group XIa-XVIII/XX-XXII/XXIV are not at all related because the antibodies/polypeptides of the Groups of Group XXII/XXVI are not used in any of the methods of XIa-XVIII/XX-XXII/XXIV

The inventions of Groups XXIII/XXVand the methods of the Groups of Group I-XI are not at all related because the nucleic acids of the Groups of Group XXII/XXVI are not used in any of the methods of I-XI.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Group XIX is further subject to election of a single disclosed species.

Claim 12 is generic to a plurality of disclosed patentably distinct species comprising antiangiogenic agents with different structures and functions wherein the antiangiogenic agents are (a) AGM-1470(TNP-470), (b) platelet factor 4, © angiostatin, all of claim 13.

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is

(703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
September 10, 2002